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Traditional methods of providing psychosocial interventions for cancer patients are associated with positive patient outcomes but have limited overall impact attributable to low participation rates. The purpose of this project is to implement and evaluate the efficacy of a computer-based psychosocial intervention for women with breast cancer. At the end of the first year of funding, we have successfully pilot-tested and implemented the SURVIVE intervention, and results from the first year are summarized in this annual report. Briefly, SURVIVE has received media attention at the local, state, and national level, yielding a number of referrals to the protocol. Additionally, 38 women have been screened in the UAB breast cancer clinics, and of these 38 women, 19 (50%) have agreed to participate. Recruitment efforts have targeted three weekly cancer clinics at UAB, and efforts to expand recruitment to two additional Birmingham-area hospitals (Medical Center East and Brookwood Hospital) are underway. 10 women with clinical stage I or II disease have been randomized into the protocol, and an additional 4 women with advanced stage disease are currently participating in the intervention. An additional 10 women will be randomized into the protocol by June 23, 2001. No data analysis has yet been undertaken.

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Introduction

The following annual report elaborates progress made towards implementation of an Internet-based psychosocial intervention, ***SURVIVE***, designed to provide information, support, and patient resources to breast cancer patients. The foundations of this intervention were completed as part of the trainee's master's thesis. These foundations include the development of a PERL 5.0 program that manages confidential communications between patients and the trainee's host computer over the Internet, the creation of a patient resource database specific to central Alabama, development of 6 structured intervention modules, and the establishment of a patient referral network. The SURVIVE Web site can be visited at http://health.psy.uab.edu/survive using the password "GUEST." A large body of literature indicates that psychosocial support interventions for cancer patients, which provide specific cognitive-behavioral and coping-skills training, are effective in the reduction of cancer pain[1-5], nausea[6-10], depression[11-15], and anxiety[16-20], and may improve indices of survival[21-25]. However, few patients take advantage of available support groups[26-27], and these support groups do not typically provide the structured components demonstrated to result in positive outcomes.[27-30] In our interactions with newly-diagnosed breast cancer patients, patients also cite logistical constraints (e.g. travel distance or lack of information) as reasons for non-participation. Through the implementation of the currently-funded protocol, SURVIVE, substantial progress has been made in making structured supportive/ informational group services more readily available to breast cancer patients. Documentation of this progress is contained herein.

Traditional methods of providing psychosocial interventions for cancer patients are associated with positive patient outcomes but have limited overall impact attributable to low participation rates. The purpose of this project is to implement and evaluate the efficacy of a computer-based psychosocial intervention for women with breast cancer. At the end of the first year of funding, we have successfully pilot-tested and implemented the SURVIVE intervention, and results from the first year are summarized in this annual report. Briefly, SURVIVE has received media attention at the local, state, and national level, yielding a number of referrals to the protocol. Additionally, 38 women have been screened in the UAB breast cancer clinics, and of these 38 women, 19 (50%) have agreed to participate. Recruitment efforts have targeted three weekly cancer clinics at UAB, and efforts to expand recruitment to two additional Birmingham-area hospitals (Medical Center East and Brookwood Hospital) are underway. 10 women with clinical stage I or II disease have been randomized into the protocol, and an additional 4 women with advanced stage disease are currently participating in the intervention. An additional 10 women will be randomized into the protocol by June 23, 2001. No data analysis has yet been undertaken.

Substantial progress has been made for each current task from the "Statement of Work" approved in the original proposal.

Task 1. Identification and Enrollment of Patients, Months 1-3:

a. Investigator will attend three UAB breast cancer clinics weekly (UAB Breast Cancer Clinic meets Monday 8am-1pm and Wednesday 1pm-5pm; UAB Interdisciplinary Breast Care Clinic meets Thursday 1pm-5pm) to recruit patients
b. All patients within 6 months of diagnosis will be identified through Lisle Nabell, M.D. and Madeline Harris, R.N. at the three clinics.
c. Investigator will visit with each patient in the exam rooms of the clinic to describe the SURVIVE program and to have interested participants sign the informed consent form.

Progress Made in Accomplishing Task 1

Recruitment efforts have been focused on three clinics at the UAB Comprehensive Cancer Clinic. In the *UAB Breast Cancer Clinic*, patients are identified through a computer database that matches patients with clinical trials for which they are eligible. The predoctoral researcher has been meeting with patients in this clinic on Monday mornings and Wednesday afternoons to provide them with information about the study. In the *Carpenter Breast Cancer Clinic*, patients who are being followed after attending the Interdisciplinary Breast Care Clinic are provided with information about the study. Finally, in the *UAB Supportive Care Clinic*, all eligible patients are provided with information about the study. The predoctoral researcher has been responsible for all recruitment efforts to date, and 38 eligible women have been screened for participation (see Appendix A). Dr. Tucker and Mr. Owen are currently training research assistants to assist with the recruitment effort. Eric Yarbrough, Sjouke Liem, and Betty Rupp are undergraduate psychology students who will be working with Dr. Tucker and Mr. Owen to enhance recruitment efforts through these three clinics.

Task 2. Evaluation of a SURVIVE Pilot Group, Months 2-4:

a. Two groups of 6-10 interested patients each will be provided with the existing SURVIVE intervention.
b. Upon completion of the 6-week program, patient de-briefing will be conducted to qualitatively assess the strengths and weaknesses of the SURVIVE program.
c. Based on patient criticisms, changes to the program may be implemented.

Progress Made in Accomplishing Task 2

Prior to final acceptance and approval of the currently funded protocol, two groups of breast cancer patients participated in a pilot version of the SURVIVE intervention protocol. A total of 16 patients participated in these pilot groups. No negative comments about the intervention were provided, and all women indicated through personal communication with the predoctoral researcher that they enjoyed participating in the groups and were appreciative of being able to be a member of a group. However, the pilot participants did offer several useful suggestions for changing the intervention program. Suggestions included making it easier to navigate the web site, making it easier to find and complete the coping exercises, and allowing participants to submit messages from the website rather than through email. An attempt was made to address each of these suggestions, and the final version of the program can be viewed at the following url: http://health.psy.uab.edu/survive. Additional changes to the intervention program were made by analyzing "hits" tracked over the course of the pilot. Results suggest that participants made far greater use of the support group bulletin board and coping exercises than other areas of the site. Efforts to improve the layout and accessibility of these areas of the site have been made.

Task 3. Increased Patient Recruitment at Other Birmingham Hospitals, Months 6-24:

a. Three honors undergraduate research assistants will participate in recruitment of patients at Medical Center East (collaborating with Kathy Fox, R.N.), Baptist Medical Center (collaborating with Pat Reymann, R.N.), and Brookwood Medical Center (collaborating with Lisa Miller, R.N.)
b. All patients within 6 months of diagnosis will be asked by collaborating nurses if they can be contacted by telephone to receive information about an Internet-based support and information service.
c. Research assistants will be trained by the investigator and faculty mentor, Diane Tucker, Ph.D, to make patient contact telephone calls.
d. Patients who provide verbal consent to be contacted will be telephoned and given information about the services provided through participation in the SURVIVE study.
e. Collaborating nurses will be provided with information pamphlets about SURVIVE to distribute to all patients. Pamphlets will contain information about contacting the principal investigator.
f. Research assistants will return calls from interested patients.

Progress Made in Accomplishing Task 3

The protocol is currently under review at Medical Center East and Brookwood Medical Center in Birmingham, AL. Four research assistants are currently working on the project: EricYarbrough, Tamika Spencer, Kiran Lagisetty, and Ford Baxter. Additionally, recruitment letters and business-reply postcards were provided to all Hematology/Oncology nurses and staff members during an organizational meeting on February 6, 2001. An overview of community outreach efforts is provided in Appendix B.

Task 4. Implementation of the SURVIVE Supportive Informational Intervention, Months 6-24:

a. Participants will be randomized to either the SURVIVE intervention or a control group.
b. Each cohort of 6-10 patients randomized to the SURVIVE intervention will be organized into an E-mail discussion group using PostOffice software.

c. Patients will be encouraged to send an introductory E-mail to the group describing their diagnosis, treatment, and current primary concerns.
d. Each week, the investigator will e-mail a new coping module to each enrolled patient, in addition to providing the participant with information to access the coping modules on the World Wide Web through the SURVIVE web site.
e. Patients will be provided with "homework" questions for each module and encouraged by the investigator to communicate with other patients by E-mail about their personal experience with each module
f. Patients will be prompted to complete the Web-based questionnaires at each collection point
g. Participants who complete the 6-week intervention will be encouraged to continue their participation with other group members without formal intervention by the investigator

Progress Made in Accomplishing Task 4

The SURVIVE intervention has been implemented as described in Task 4. To date, 10 participants (cohort 1) have been randomized to receive either the intervention or a waiting-list control condition. An additional 12 participants have recently been recruited (cohort 2) and will soon be randomized. Cohort 1 is nearing the end of the intervention. A structured system of prompting participants to introduce themselves to the group and to engage in coping exercises is currently in place. All homework exercises completed from the coping web pages are stored on the server that administers the project. Participants have been completing the questionnaire battery in paper-and-pencil format. All questionnaires are currently being mailed to participants, and the return rate has been 100%. All data are then entered by hand and stored in a Microsoft Excel database.

Task 5. Data Reduction and Analysis, Months 25-28.

a. Outcome data on health-related quality of life, depression/anxiety, patient satisfaction, coping, self-efficacy for coping, and positive contributions will be analyzed using SAS ver 8.0.
b. A 2 x 3 repeated measures analysis of variance will be performed for each primary dependent variable (HRQOL, satisfaction, anxiety, and depression) using a between-groups factor (control vs. intervention) and a within-groups factor (pre-test, 6-weeks, & 6-months).
c. Follow-up analyses of significant main or interaction effects will be conducted, using hierarchical regression to evaluate potential mediating factors such as coping, self-efficacy for coping, positive contributions, and frequency of program participation.
d. Structural equation modeling will be conducted using LISREL. Primary dependent variables without significant main or interaction effects in task 5b will not be included in the structural equation model. This analysis will only be performed if enough participants are enrolled (n>120) over the course of the study.

Progress Made in Accomplishing Task 5

Preliminary descriptive data analysis has been conducted on the data obtained from the first ten participants. Due to the small sample size, only a few notable findings are reported here. First, depression scores are moderate but do not appear to be clinically elevated in this sample (mean = 7.9 on the Hospital Anxiety and Depression Scale). Second, anxiety scores are clinically elevated (mean = 11.9, range = 7-15), which indicates a substantial degree of anxiety among the study participants.

Post-test measures for cohort 1 will be mailed on 6/23/01 in order to obtain post-test results which will allow for longitudinal analysis. Further data analysis will be delayed until recruitment goals have been met and sample size is sufficient to warrant protocol evaluation.

Task 6. Dissemination of Research Findings, Months 29-36.

a. Multiple manuscripts will be prepared:
    1. A descriptive paper regarding the use of interactive Web programming to provide psychosocial support and information, the collection of psychological data over the Internet, and the establishment of patient referral services to increase patient participation in social support services available in Comprehensive Cancer Centers. (submission to Journal of Psychosocial Oncology)
    2. A paper describing the intervention and initial 6-week follow-up results for primary dependent variables (submission to Health Psychology)
    3. A paper examining inter-correlations between changes in mediating variables and changes in primary dependent variables, including SEM analyses (submission to Psycho-Oncology)
    4. A paper describing results of the 6-month follow-up evaluations (submission to Health Psychology)
b. Results of the study will be summarized and presented to all participating clinics and hospitals.
c. Posters will be presented at annual meetings of the Society of Behavioral Medicine and at the event sponsored by the DOD to describe ongoing progress of the study.

Progress Made in Accomplishing Task 6

A draft manuscript, entitled "Breast cancer support and information using the Internet: characterizing access and interest in participation," is currently in preparation. I plan to submit this manuscript to the *Journal of Psychosocial Oncology* in July, 2001. A summary of additional efforts to disseminate the goals and preliminary findings of the protocol can be found in the "Reportable Outcomes" section of this report.

Key Research Accomplishments.

- Completion of pilot testing
- Completion of automated coping exercises for web site
- Successful recruitment plan implementation
- Establishment of recruitment tracking, outreach effort, and outcomes databases
- Dissemination of findings to UAB academic departments, the Birmingham community, and national professional organizations
- Enrollment of first cohort of participants

Reportable Outcomes. Ongoing dissemination efforts for DAMD17-00-1-0121.

Published Papers

Owen, J.E.; Klapow, J.C.; Hicken, B.; and Tucker, D. (2001). "Psychosocial interventions for cancer patients: Review of outcomes using a three-dimensional model." *Psycho-Oncology*, 10, 218-230.

Owen, J.E.; Klapow, J.C.; and Casebeer, L. (2000). "Evaluating the relationship between pain presentation and health-related quality of life in outpatients with metastatic or recurrent neoplastic disease." *Quality of Life Research, 9, 855-863.*

Presentations

Owen, J.E. (May, 2001). "Providing psychological therapies for cancer over the Internet: Rationale, findings, and directions." Invited presentation to the UAB School of Nursing, May 16, 2001.

Owen, J.E. (April, 2001). "Using the Internet to Bring Behavioral Medicine to Cancer Patients: Development and Early Evidence from a Small Group Intervention ." Invited presentation to the M.D. Anderson Department of Behavioral Science, Houston, Texas, April 22, 2001.

Owen, J.E. (April, 2001). "Treating Cancer-Related Distress Online: Feasibility, Development, and Preliminary Results from SURVIVE." Invited presentation to the UAB Department of Health Behavior, April 17, 2001.

Owen, J.E., Klapow, J.C., Donovan, K.A., Yarbrough, E., & Tucker, D.C. (March, 2001). "Cognitive processing and emotional disclosure on the Internet: Structured therapy groups versus online discussion groups for women with breast cancer." Poster presented at the 59th Annual Meeting of the American Psychosomatic Society in Monterey, CA on March 8, 2001.

Conclusion

Considerable progress has been made since initial funding was awarded for this project. Progress from the original Statement of Work is currently on or ahead of schedule for each major task. Pilot testing has been completed, and recruitment numbers for the trial are on target for meeting initial sample size goals. Patients who are approached for participation in the study have overwhelmingly indicated positive perceptions of the study, and recruitment rates are approximately 50% to date-considerably higher than rates published in previous psychosocial interventions for cancer. In the next year of funding, we hope to recruit the remainder of our participants and to continue to collect outcomes data from current participants. No problems have been encountered that could jeopardize our ability to successfully complete the implementation of this trial. We remain excited by the potential reach of this project.

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Appendix A. Breast cancer patients approached with information about DAMD17-00-1-0121 and expressed interest or reasons for declining participation.

Patient Number	Agreement to Participate in the Study	Reason for Declining Participation
1	INELIGIBLE	Participating in another UAB support group study
2	MAYBE	computer not set-up yet, will contact us if interested
3	MAYBE	still making treatment decisions; will call to let us know
4	MAYBE	interested but took information to make a decision on her own.
5	MAYBE	does not yet have computer; expects to have one in June
6	NO	no reason provided
7	NO	no reason provided
8	NO	has support; prefers face-to-face over computer; time is restricted by work
9	NO	no access to a computer
10	NO	has adequate support at home.
11	NO	too busy.
12	NO	doesn't use computers
13	NO	no reason provided
14	NO	no computer
15	NO	no computer; unwilling to travel to a library
16	NO	no reason provided
17	NO	does not have a computer.
18	NO	no access to a computer
19	NO	doesn't feel comfortable using the Internet
20	YES	NA
21	YES	NA
22	YES	NA
23	YES	NA
24	YES	NA
25	YES	NA
26	YES	NA
27	YES	NA
28	YES	NA
29	YES	NA
30	YES	NA
31	YES	NA
32	YES	NA
33	YES	NA
34	YES	NA
35	YES	NA
36	YES	NA
37	YES	NA
38	YES	NA

Appendix B. Overview of community outreach efforts for DAMD17-00-1-0121.

Date	*Media or Outreach Effort*	*Brief Description*
2/3/2001	Mobile Register Article	Brief newspaper article
1/28/01-2/3/01	UAB Home Page	Link to the SURVIVE web site provided from the UAB Home Page
1/29/2001	UAB CancerNews Monthly e-Newsletter	Brief information link providing information about Survive
2/5/2001	UAB Reporter Article	Front Page Article in UAB Reporter
2/5/2001	Lisle Nabell	Met with Dr. Nabell to discuss recruitment efforts
2/6/2001	Hem/Onc Nurses Meeting	Talked with nurses about Recruitment, provided recruitment materials to all nurses and staff
2/9/2001	Hem/Onc	Put up 4 posters in exam rooms; provided 2 magazine racks with 40 recruitment envelopes each to the nurse clinic coordinator
2/13/2001	UAB Health System	Links to survive added to UAB Health System website (http://www.health.uab.edu)
2/15/2001	Health InfoNet of Jefferson County	Links to survive added to web site: http://www.uab.edu/infonet/
2/22/2001	American Cancer Society	Met with Lori Langner to discuss education of Reach to Recovery volunteers, potential link to web ACS web site
2/23/2001	Hem/Onc	Put up 9 additional posters in the exam rooms; all exam rooms now have a recruitment poster stocked with business-reply postcards
2/27/2001	UAB Kaleidoscope	Article on p.7-8 of student newspaper
3/1/2001	UAB Health System web site	Link to information about survive added to web site: http://www.health.uab.edu/show.asp?durki=36799
3/3/2001	UAB Health Check	Health fair held at the Riverchase Galleria, information about Survive distributed
3/5/2001	Meeting w/ Duck-Hee Kang and Teri Mobley	Discussed potential recruitment overlap and brainstormed ideas for avoiding double recruitment
3/15/2001	WebMD	Published brief review of APS abstract (Denise Mann: 212-721-2836)
4/2001	Interview with USA Today reporter	Talked briefly with Marilyn Elias about the project.
5/2001	Birmingham Post-Herald Article	Brief, 1-page article describing the project